REMARKS

Claim 24 was pending in this application. Following entry of the amendment and new claims, claims 24 and 58-60 will be pending and under examination in this application. In the Action, the Examiner rejected claim 24 under 35 U.S.C. §102(b) as assertedly anticipated over Small et al. (US Patent 4,101,460) (hereinafter "Small"), and Bostick et al., (US Patent 4,263,406) (hereinafter "Bostick"). Applicants request reconsideration in light of the following remarks.

I. Support or Amendment to the Claims

Support for the amendment to claim 24 and new claims 58 to 60 is found, for example, at page 6, lines 21-26, and at page 20, line 30, to page 21, line 29, which disclose that the detection means comprises a detection reagent which binds to glycosaminoglycans, and which may be a metachromatic dye, such as dimethylmethylene blue (DMMB).

The amendment and new claims include no new matter.

II. Patentability

A. The rejection of claim 24 under 35 U.S.C. §102(b) as anticipated by Small should be withdrawn

The Examiner rejected claim 24 under 35 U.S.C. §102(b) as anticipated by the disclosure of Small. The Examiner asserts that Small discloses a device that separates ions using ion-exchange chromatography, and as such is capable of measuring and detecting glycosaminoglycans (GAGs). Applicants respectfully disagree.

Claim 24 as amended is directed to a glycosaminoglycan measuring device wherein the detection means comprises is a detection reagent that binds glycosaminoglycans. Small is directed to a composition comprising an ion exchange resin, and discloses that the composition of the invention could be used in an anion exchange column to separate ions, and that the ions could then be detected via light scatter in a spectrophotometer. The ions for separation described by Small include traditional monovalent or divalent ions such as Cl-, Br-, NO_2-, and SO_4^{-2}, to name a few.

For a reference to anticipate, each and every element of the invention must be disclosed in the single reference, and the reference must be enabling. A GAG molecule is not a traditional ion as the Examiner is asserting, but is a larger polyionic moiety with a more complex binding structure and affinity compared to the traditional ions separated by Small. GAG molecules are polyanions, which comprises multiple ionic charges, in contrast to the ions described by Small. Small does not disclose the conditions under which the composition or device of Small is enabled to separate and measure large polyionic molecules such as GAGs and the Examiner has not provided evidence that the device disclosed in Small can be used to separate and detect such large polyionic molecules. For detection means, Small employs direct photometric detection of the separated ions, not indirect detection, whereby a reagent that binds to the separated molecules is detected, as claimed herein. Moreover, Small does not disclose the specific means for detecting GAGs using reagents that bind to the glycosaminoglycans as claimed herein, such as a metachromatic dye. Thus, Small does not disclose a GAG measuring device as presently claimed and the rejection of claim 24 as anticipated by Small should be withdrawn.

B. The rejection of claim 24 under 35 U.S.C. §102(b) as anticipated by Bostick should be withdrawn

The Examiner rejected claim 24 under 35 U.S.C. §102(b) as anticipated by the disclosure of Bostick. The Examiner asserts that Bostick discloses a device having an ion-exchange resin as an ion separator, and therefore is capable of measuring and detecting GAGs. Applicants respectfully disagree.

As stated above, claim 24 as amended is directed to a glycosaminoglycan measuring device wherein the detection means comprises a detection reagent that binds the glycosaminoglycans. Bostick discloses an apparatus having an ion exchange column for separating a particular indicator species (e.g., isoenzymes) from a reaction solution, and discloses that components in the columns' effluent can be measured by comparative photometric means. Bostick teaches that a sample of interest is separated into two sample streams, one of which is a reference stream and the other of which is useful to react the sample protein (enzyme) with a substrate in order to detect the reaction of the enzyme with

the substrate, and detect turnover of the enzyme using an indicator species (see col. 5, lines 1-27).

Bostick does not disclose the conditions under which the apparatus of Bostick is enabled to separate and detect GAG moieties, which are not enzymes; and the Examiner has not provided evidence that the device disclosed in Bostick can be used to separate and detect GAG moieties. For detection means, Bostick employs direct photometric detection of the products of the enzymatic activity of separated isoenzymes. This detection means could not possibly work to detect GAG moieties because GAGs are not enzymes, and thus do not generate products. Further, Bostick does not use as detection means a reagent that binds to the separated molecules, as claimed herein, and, in particular, does not disclose detection of separated GAGs using a detection reagent that binds to the GAGs as claimed herein, such as a metachromatic dye. Thus, Bostick does not disclose a GAG measuring device as presently claimed and the rejection of claim 24 as anticipated by Bostick should be withdrawn.

III. Conclusion

Applicant submits that the application is in condition for allowance and respectfully request expedited notification of the same.

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Respectfully submitted,

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